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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,231	01/18/2001	Deborah J. Phippard	3221-US	7382

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EXAMINER

CHEN, LIPING

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,231

Applicant(s)

PHIPPARD ET AL.

Examiner

Liping Chen

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 10-13, 18, 23-25, and 28-29, drawn to a nucleic acid, a methods for producing and purifying a polypeptide, and host cells, classified in 435, subclass 69.1.
- II. Claims 8-9 drawn to a method of identifying a nucleic acid by hybridization using detectably labeled nucleic acid probe, classified in 435, subclass 6.
- III. Claims 14 and 26 drawn to a purified protein, classified in class 530, subclass 350⁺.
- IV. Claims 15, and 27, drawn to an antibody that binds to a purified protein, classified in 530, subclass 387.1.
- V. Claims 16-17, drawn to a transgenic animal, classified in class 800, subclass 13
- VI. Claim 19, drawn to a method of identifying a biologically active composition using a sample comprising a protein, classified in 435, subclass 7.1.
- VII. Claim 20, drawn to an undisclosed compound that is detectable using a sample comprising a protein, not classifiable.
- VIII. Claims 21 and 22, drawn to a computer-readable medium and the method of using for nucleic acid sequence analysis, classified in 702, subclass 19, or 20.
- IX. Claim 30, drawn to a diagnosis method of osteoarthritis by nucleotide homology comparison of expressed mRNA or cDNA with at least 20 nucleotides identical to nucleic acid sequence compared, classified in 435, subclass 6.
- X. Claim 31, drawn to a method of isolating a nucleic acid, classified in 435, subclass 6.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

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used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of invention I can be used to produce protein *in vitro*.

Inventions I and III are two distinct products. The nucleic acid of invention I can be used for nucleic acid hybridization assay. The protein of invention III can be used to produce antibody.

Inventions I and IV are two distinct products. The nucleic acid of invention I can be used for nucleic acid hybridization assay. The antibody of invention IV can be used to detect protein.

Inventions I and V are two distinct products. The nucleic acid of invention I can be used for nucleic acid hybridization assay. The animal of invention V can be used to observe gene function, or as models for disease or condition.

Inventions I and VI are mutually exclusive and independent. The nucleic acid of invention I is not needed for identifying a biologically active composition using a sample comprising a protein of invention VI, and vice versa.

Inventions I and VII are mutually exclusive and independent. The nucleic acid of invention I is not required for the compound of invention VII, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Inventions I and VIII are mutually exclusive and independent. The nucleic acid of invention I is not used in invention VIII, and vice versa. The nucleic acid sequence used in the analysis of invention VIII is a representation of the nucleic acid of invention I. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of invention I can be used to produce protein *in vitro*.

Inventions I and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to

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make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case nucleic acid of invention I can be produced by bench top nucleic acid synthesis.

Invention II and any one of inventions III-VII are mutually exclusive and independent. The method for identifying a nucleic acid of invention II is not needed for the implementation of the purified protein of invention III, the antibody of invention IV, the transgenic animal of invention V, a method of identifying a biologically active composition using a sample comprising a protein of invention VI, and an undisclosed compound that is detectable using a sample comprising a protein of invention VII, and vice versa. Further, each invention requires materially different and separate protocols for implementation.

Inventions II and VIII are mutually exclusive and independent. The method for identifying a nucleic acid of invention II is not needed to implement the computer-readable medium of invention VIII, and vice versa. Further more, each of the method of II and VIII requires a separate and materially different protocol.

Inventions II and IX are mutually exclusive and independent. The method for identifying a nucleic acid of invention II is not needed for the method for diagnosis of osteoarthritis of invention IX, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions II and X are mutually exclusive and independent. The method for identifying a nucleic acid of invention II is not needed for the method for isolating a nucleic acid of invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention III and invention IV are two distinct products because they are of separate uses. The protein of invention III can be used in a protocol to produce antibodies and the antibody of invention IV can be used in immunological assays.

Invention III and either inventions V and VII are mutually exclusive and independent. The protein of invention III is not needed for transgenic animal of invention V or an undisclosed compound that is detectable using a sample comprising a protein of invention VII as the compound can be nucleic

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acid that has protein binding sites, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of protein of invention III can be used to produce antibody.

Invention III and any one of inventions VIII-X are mutually exclusive and independent. The purified protein of invention III is not used in a method of identifying a nucleic acid through a computer-readable medium of invention VIII, a method of diagnosis of osteoarthritis by analysis of expressed mRNA of invention IX or a method of isolating a nucleic acid of invention X, and visa versa. .

Furthermore, each invention requires materially different and separate protocols.

Invention IV and either inventions V and VII are mutually exclusive and independent products. The antibody of invention IV is not needed for a transgenic animal of invention V or an undisclosed compound that is detectable using a sample comprising a protein of invention VII, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of invention IV can be used in immunological assays.

Invention IV and any one of inventions VIII-X are mutually exclusive and independent. The antibody of invention IV is not used in a method of identifying a nucleic acid through a computer-readable medium of invention VIII, a method of diagnosis of osteoarthritis by analysis of expressed mRNA of invention IX or a method of isolating a nucleic acid of invention X, and visa versa. Furthermore, each invention requires materially different and separate protocols.

Inventions V and VI are mutually exclusive and independent. The animal of invention V is not used in the method for identifying a biologically active composition using a sample comprising a protein of invention VI, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Inventions V and VII are two distinct products capable of separate use. The transgenic animal of invention V can be used as a model for disease treatment. The undisclosed compound of invention VII can be used to study protein-protein interaction.

Invention V and any one of inventions VIII-X are distinct. The animal of invention V is not used in a method of identifying a nucleic acid through a computer-readable medium of invention VIII, a method for diagnosis of osteoarthritis by analysis of expressed mRNA or DNA of invention IX, or a method of isolating a nucleic acid of invention X, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Inventions VI and VII are mutually exclusive and independent. The method of identifying a biologically active composition of invention VI is not required for the undisclosed compound of invention VII, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Invention VI and any one of inventions VIII-X are mutually exclusive and independent. The method for identifying a biologically active composition using a sample comprising a protein of invention VI is not needed for the implementation of a method of identifying a nucleic acid through a computer-readable medium of invention VIII, analyzing expressed mRNA or cDNA of invention IX and isolating a nucleic acid of invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention VII and any one of inventions VIII-X are mutually exclusive and independent. The undisclosed compound of invention VII is not required for the method of identifying a nucleic acid through a computer-readable medium of invention VIII, a method of diagnosis of osteoarthritis by analysis of expressed mRNA or cDNA of invention IX and a method of isolating a nucleic acid of invention X, and vice versa. Furthermore, each invention requires materially different and separate protocols.

Invention VIII and either inventions IX and X are mutually exclusive and independent. The method of identifying a nucleic acid through a computer-readable medium of invention VIII is not needed for the implementation of a method of diagnosis of osteoarthritis by analyzing expressed mRNA or cDNA of invention IX and isolating a nucleic acid of invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions IX and X are mutually exclusive and independent. The method of diagnosis of osteoarthritis by analysis of expressed mRNA or cDNA of invention IX is not needed for the implementation of isolating a nucleic acid of invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

The specification discloses SEQ NO 1-82. Applicant is required to elect one SEQ NO for examination purposes. Should applicant choose to do so, any sequences fully embedded in the elected sequence will also be examined. Applicant is required to identify any such embedded sequences and there cannot be any over laps with other sequences not in the elected sequence.

Because these inventions are distinct for the reasons given, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632
March 20, 2002


DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1600-1632